

REMARKS

The present Office Actions addresses and rejects claims 1-17. Reconsideration is respectfully requested in view of the following remarks.

Claim Rejections

Claims 1-17 continue to be rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,179,225 of Shluzas et al. Applicants respectfully disagree.

Claims 1-10

Independent claim 1 recites a minimally invasive surgical method that includes identifying a muscle plane and inserting a substantially planar blunt tip of a tool through the incision while manipulating the blunt tip along the muscle plane extending between the incision and the vertebra to separate the muscle. Shluzas does not teach or even suggest any of the recited method steps.

(1) “Identifying A Muscle Plane”

The Examiner argues that Shluzas discloses making an incision and inserting a guide wire, and that “[i]n order to perform this step, some regard to a muscle plane must be address by the surgeon to determine the location of the incision.” Oct. 22, 2007 Office Action, p. 3. The Examiner thus argues that “identifying a muscle plane,” as required by claim 1, is an inherent feature of Shluzas.

In order for a reference to inherently anticipate, the claimed limitation must be necessarily present in the disclosure. Shluzas method does not necessarily require that the muscle plane be identified. To the contrary, the method is performed without any regard to the muscle plane. Muscles are formed from bundles of fibers, and a muscle *plane* is a location at which two different muscles can be separated from one another. A muscle *plane* does not need to be identified in order to determine the location of an incision, or to insert a guide wire or other tool through the muscle. Typically, a surgeon forms the incision at a desired location above the desired surgical site. The incision is formed regardless of the muscle plane, as the incision is made in the tissue and not in the muscles underlying the tissue. While the surgeon may understand what muscles lie beneath the tissue being incised, the muscle *plane* is

certainly not identified and there is no need to identify the muscle plane in order to form the incision, as suggested by the Examiner.

There is also no need to identify the muscle plane in order to insert the guide wire through the muscles. As explained at Col. 22, lines 22-43 of Shluzas, a guide wire is introduced through the skin, fascia, and muscle to the surgical site, then a series of dilators are used to sequentially expand the incision followed by placement of an access device (i.e., the retractor) for providing a pathway to the surgical site. Since the guide wire extends along a straight path and cuts through the muscles, the muscle plane is not identified. Shluzas simply lacks any teaching, literal or inherent, of a method that includes identifying a muscle plane.

(2) "Inserting A Substantially Planar Blunt Tip Of A Tool Through The Incision While Manipulating The Blunt Tip Along The Muscle Plane Extending Between The Incision And The Vertebra To Separate The Muscles"

The Examiner further argues that Shluzas discloses “inserting a substantially planar blunt tip of a tool through the incision while manipulating the blunt tip along the muscle plane extending between the incision and the vertebra to separate the muscles,” as further required by claim 1. The Examiner asserts that the retractor, or the tools shown in Figures 51 and 52, can be considered to have a blunt end, and that each of these tools is inserted through the incision. The Examiner does not provide any support for the limitation that the tool be manipulated along the muscle plane to separate the muscles, but rather merely states that the retractor is “interpreted as that which aids in providing access separating the muscles.” *Id.* at p. 2. Applicants respectfully disagree.

At the outset, the retractor, as shown in Figures 2 and 3 for example, has a generally hollow cylindrical shape. The distal portion is expandable to provide increased access to a surgical site. No person having ordinary skill in the art would consider a hollow cylindrical body to be blunt. Blunt is generally understood to mean dull, not-sharp. A hollow cylinder certainly does not have a dull, non-sharp end. To the contrary, the cylindrical end could be considered to be sharp, as it would likely cut through tissue. With regard to the tools shown in Figures 51 and 52, while these tools could be considered to have blunt ends, neither tool is inserted through the incision and used to separate a muscle plane. Rather, the tools shown in Figures 51 and 52 are inserted through the retractor.

Regardless of whether Shluzas discloses a blunt tip tool, Shluzas does not teach or even suggest manipulating any tool *along a muscle plane* to separate the muscles. As previously explained above, Shluzas discloses inserting a guide wire *through* the muscles – not along a muscle *plane* formed between muscles - and dilating the muscles using a series of dilators inserted over the guide wire. The retractor is then inserted over the dilators. Since the guide wire is merely penetrated through the muscles, the guide wire is not inserted along a muscle plane. Moreover, there is no teaching or suggestion to *manipulate* the tool to separate the muscle plane. Shluzas simply does not contain any teaching to identify a muscle plane, much less to manipulate a tool to separate the muscles along a plane. The procedure disclosed by Shluzas is the exact problem Applicant's invention improves upon. Insertion of a guide wire and a series of dilators directly through the muscles will necessarily damage the muscles (as the guide wire cuts through the muscle, and the dilators will tear the muscle apart). Applicants have discovered that a blunt tip tool can be used to carefully separate the muscles along a muscle *plane*, and that this minimizes trauma to the patient.

Shluzas is therefore deficient for several reasons, and thus cannot anticipate claim 1. Accordingly, claim 1, as well as claims 2-10 which depend therefrom, distinguish over Shluzas and represent allowable subject matter.

Claims 11-17

Independent claim 11 recites a minimally invasive surgical method that includes making a first incision in a patient, inserting a blunt tip of a tool through the first incision and manipulating the blunt tip to create a first pathway from the first incision, between a muscle plane, to a first site on a first vertebral body, and advancing a guide wire through the tool to position a distal end of the guide wire adjacent the first site.

(1) *"Inserting A Blunt Tip Of A Tool Through The First Incision And Manipulating The Blunt Tip To Create A First Pathway From The First Incision, Between A Muscle Plane, To A First Site On A First Vertebral Body"*

As discussed above with respect to claim 1, Shluzas fails to teach, literally or inherently, any method in which a tool is inserted between a muscle plane. To the contrary, Shluzas teaches inserting a

guide wire directly into the muscle. The guide wire will necessarily penetrate the muscle. There is simply no suggestion to insert any tool along a muscle *plane*, rather than through the muscle itself.

(2) *"Advancing A Guide Wire Through The Tool To Position A Distal End Of The Guide Wire Adjacent The First Site"*

Shluzas further fails to teach advancing a guide wire through a tool to position a distal end of the guide wire adjacent a first site, as further required by claim 11. To the contrary, Shluzas' method requires that a guide wire be inserted first, and then several dilators be inserted over the guide wire to dilate the tissue. Shluzas' guide wire is never inserted through a tool, and the Examiner has failed to point to any teaching in Shluza to indicate otherwise.

Shluzas is therefore deficient for several reasons with respect to claim 11 as well, and thus Shluzas cannot anticipate claim 11. Accordingly, claim 11, as well as claims 12-17 which depend therefrom, distinguish over Shluzas and represent allowable subject matter.

Conclusion

In view of the above, Applicant believes that all claims are in condition for allowance and allowance thereof is respectfully requested.

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